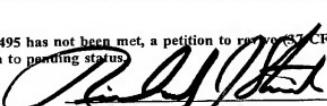


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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE <small>(REV. 9-2001)</small>		ATTORNEY'S DOCKET NUMBER CU-2691 RJS
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/009860
INTERNATIONAL APPLICATION NO. PCT/SE00/00727	INTERNATIONAL FILING DATE 17 April 2000	PRIORITY DATE CLAIMED 30 April 1999
TITLE OF INVENTION ADJUSTABLE SPINAL BRACE		
APPLICANT(S) FOR DO/EO/US Stig WILLNER		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<p>1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.</p> <p>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input checked="" type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (Article 31).</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(e)(2)) <ul style="list-style-type: none"> a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). </p> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(e)(2)). <ul style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). </p> <p>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ul style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input checked="" type="checkbox"/> have not been made and will not be made. </p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p>		
Items 11 to 20 below concern document(s) or information included:		
<p>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input checked="" type="checkbox"/> A FIRST preliminary amendment.</p> <p>14. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A change of power of attorney and/or address letter.</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p> <p>20. <input type="checkbox"/> Other items or information:</p>		
Express Mail Label No. EL698182757US		

U.S. APPLICATION NO. (If known; see 37 CFR 1.3)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER		
10/009860	PCT/SEOO/00727	CU-2691 RJS		
21. <input checked="" type="checkbox"/> The following fees are submitted:		CALCULATIONS PTO USE ONLY		
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):				
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO		\$1040.00		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO		\$890.00		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO		\$740.00		
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4)		\$710.00		
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4)		\$100.00		
ENTER APPROPRIATE BASIC FEE AMOUNT =		\$ 1040.00		
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).		\$		
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$
Total claims	14 - 20 =	0	x \$18.00	\$
Independent claims	1 - 3 =	0	x \$84.00	\$
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$280.00	\$
TOTAL OF ABOVE CALCULATIONS =		\$ 1040.00		
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.		\$ 520.00		
SUBTOTAL =		\$ 520.00		
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).		\$		
TOTAL NATIONAL FEE =		\$		
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +		\$		
TOTAL FEES ENCLOSED =		\$ 520.00		
		Amount to be refunded: \$		
		charged: \$		
<p>a. <input checked="" type="checkbox"/> A check in the amount of \$ 520.00 to cover the above fees is enclosed.</p> <p>b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>12-0400</u>. A duplicate copy of this sheet is enclosed.</p> <p>d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p>				
<p>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to review (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.</p> <p>SEND ALL CORRESPONDENCE TO: Ladas & Parry 224 South Michigan Avenue Chicago, Illinois 60604 (312) 427-1300 Customer Number 26530</p> <p>SIGNATURE  Richard J. Streit</p> <p>NAME 25765</p> <p>REGISTRATION NUMBER October 26, 2001</p>				

DOCKET: CU-2691

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

APPLICANT: Stig WILLNER et al)
TITLE: ADJUSTABLE SPINAL BRACE)
COMPLETION OF PCT/SE00/00727 filed 17 April 2000)

The Commissioner for Patents (DO/EO/US)
Box PCT
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Dear Sir:

Please amend the application being filed herewith under 35 USC 371.

IN THE CLAIMS.

Please cancel claims 1-11 from the PCT application as filed as well as claims 1-11 from the claims attached to the International Preliminary Examination Report and substitute the clean version of claims 1-11 as enclosed herewith. Also enclosed is a marked copy of the claims as attached to the International Preliminary Examination Report, showing changes made therein.

REMARKS

The aforesaid claims are based on the claims as attached to the International Preliminary Examination Report, with amendments to place the same in better condition for examination under U.S. rules of practice.

Favorable consideration of this application is respectfully requested.

Respectfully submitted,

~~Attorney for Applicant~~

October 26, 2001

Date

Richard J. Streit, Reg. 25765
c/o Ladas & Parry
224 South Michigan Avenue
Chicago, Illinois 60604
(312) 427-1300

CLAIMS

1. An adjustable spinal brace comprising an anterior abdominal pad, a posterior frame and lateral iliac rolls, said iliac rolls to be positioned at the top of the pelvis bone, and the abdominal pad and the posterior frame being interconnected by a connection means, wherein the connection means comprises said iliac rolls and straps to be connected to the anterior abdominal pad, and the posterior frame has an adjustable lumbar pad provided with pressure setting means for setting the distance between the lumbar pad and the posterior frame, thereby enabling an adjustment of the applied pressure.

2. A spinal brace according to claim 1, wherein the lumbar pad also is adjustable in height.

3. A spinal brace according to claim 1, wherein the pressure setting means comprises a screw jack.

4. A spinal brace according to claim 3, wherein the screw jack comprises a vertically placed adjusting screw.

5. A spinal brace according to claim 3, wherein the position of the screw of the screw jack is adjustable in the lateral direction.

6. A spinal brace according to claim 1, wherein the posterior frame comprises two vertical struts, a cranial horizontal support and a caudal horizontal support.

7. A spinal brace according to claim 6, wherein the cranial horizontal support and the caudal horizontal supports are adjustable in height.

8. A spinal brace according to claim 1, wherein straps are provided between the iliac rolls and the abdominal pad.

9. A spinal brace according to claim 6, wherein straps are provided between the horizontal supports and the abdominal pad.

10. A spinal brace according to claim 8, wherein straps are provided between the horizontal supports and the abdominal pad.

11. A spinal brace according to claim 1, wherein the anterior abdominal pad is lightweight and concave and adapted to cover the abdomen substantially from the symphysis to the sternum point.
12. A spinal brace according to claim 6, wherein the anterior abdominal pad is lightweight and concave and adapted to cover the abdomen substantially from the symphysis to the sternum point.
13. A spinal brace according to claim 8, wherein the anterior abdominal pad is lightweight and concave and adapted to cover the abdomen substantially from the symphysis to the sternum point.
14. A spinal brace according to claim 11, wherein the cranial border of the anterior abdominal pad is shaped after the lower ribs.

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CLAIMS

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1. An adjustable spinal brace comprising an anterior abdominal pad (27), a posterior frame (11) and lateral iliac rolls (23), said iliac rolls (23) to be positioned at the top of the pelvis bone (*os sacrum*), and the abdominal pad (27) and the posterior frame (11) being interconnected by a connection means, *characterised in that* the connection means comprises said iliac rolls (23) and straps (41) to be connected to the anterior abdominal pad (27), and *in that* the posterior frame (11) has an adjustable lumbar pad (22) provided with pressure setting means (85) for setting the distance between the lumbar pad (22) and the posterior frame (11), thereby enabling an adjustment of the applied pressure.
2. A spinal brace according to claim 1, *wherein* the lumbar pad also (22) is adjustable in height.
3. A spinal brace according to claim 1 or 2, *wherein* the pressure setting means comprises a screw jack (8, 16).
4. A spinal brace according to claim 3, *wherein* the screw jack comprises a vertically placed adjusting screw (8).
5. A spinal brace according to claim 3 or 4, *wherein* the position of the screw (8) of the screw jack is adjustable in the lateral direction.
6. A spinal brace according to any of the previous claims, *wherein* the posterior frame (11) comprises two vertical struts (12), a cranial horizontal support (68) and a caudal horizontal support (67).
7. A spinal brace according to claim 6, *wherein* the cranial horizontal support (68) and the caudal horizontal supports (67) are adjustable in height.
8. A spinal brace according to any of the previous claims, *wherein* that straps (41) are provided between the iliac rolls (23) and the abdominal pad (27).
9. A spinal brace according to claim 8 and 6 or 7, *wherein* the straps (41) are provided between the horizontal supports (15, 6) and the abdominal pad (27).
10. A spinal brace according to any of the previous claims, *wherein* that the anterior abdominal pad (27) is lightweight and concave and adapted to cover the abdomen substantially from the symphysis to the sternum point.
11. A spinal brace according to claim 10, *wherein* the cranial border of the anterior abdominal pad (27) is shaped after the lower ribs.
12. (Same as claim 9 but make dependent on claim 8)
13. (Same as claim 11 but make dependent on claim 8)

ADJUSTABLE SPINAL BRACE

PTO/PCT Rec'd 26 OCT 2001

Field of invention

- The present invention relates to an adjustable spinal brace, and more particularly a lumbar brace, which is multi-adjustable for conservative treatment of low back pain. The spinal brace is adjustable to enable an accurate magnitude and position of the pressure to correct the curvature of the spine, especially in the lumbar area. At the same time, the design of the brace is open at the lateral sides, which allows for lateral bending and normal movement of arms and legs.
- 10

State of the art

- Various braces and other orthotic devices are known in the art. There are spinal braces with various heights, some intending to immobilise and stabilise the entire spine – thoracic as well as lumbar areas. Other types of spinal braces – low type – are only stabilising the lower part of the spine – the lumbar area.

Furthermore, the rigidity of the brace varies a lot from soft braces made of fabrics to rigid braces made of plastics. The more rigid the brace is, the more immobilising and stabilising effects are seen. That means that a rigid brace, nowadays usually prefabricated by thermoplastic materials, has a better positive pain relieving effect compared to soft and semirigid braces.

- However, because of the rigidity of the brace, a lot of negative effects are seen such as an irritating stiffness of the trunk and unpleasant diffuse pressure on the trunk. Furthermore, the pressure on the groins will negatively influence the mobility of the hips seen as difficulties to drive cars etc. Other negative effects are excessive pressure of the upper border of the rigid brace on the thoracic cage, and the rigidity also makes movements of the arms more difficult.

Not very seldom, the negative effects will exceed the positive effects. The consequence of this is that, in spite of a clear pain relief when using the brace, the patients will not accept and use the brace.

- 30 It is known that the position of the spine giving a maximal pain relief is difficult to find. Even just small changes of the degree of the lumbar lordosis and the level of this maximal support will influence the effect of the brace treatment. This position for a maximal pain relief varies from one case to another, which means that a prefabricated shaped brace will not give the patient the maximal pain relief.

Typically, prior art braces comprise frontal breast or abdominal plates or elements and anterior dorsal plates or elements interconnected by straps and rolls to apply stabilising or immobilising pressures. Examples of the prior art may be found in the US patents Nos. 2,813,526, 4,285,336 and 4,930,499. A problem with the

prior art is that it is difficult to set the exact magnitude and position of the pressure by means of tightening straps. In this connection, it is critical that the position and magnitude of the pressure applied is correct because otherwise the patient does not experience any pain relief.

- 5 As is mentioned above, another problem is that the abdominal and dorsal elements are large and encumber the movements of the body, e.g. lateral bending and movements of the arms and legs as well as sitting.

- In this technical field, a test instrument for testing spinal braces is previously known. The test instrument was developed by one of the present inventors and
10 patented in Sweden under No. 8505547-3. The test instrument includes various means for adjusting the size of the brace and magnitude and position of the applied pressure. However, this test instrument is not suitable for day to day use because the design featured protruding screws and the like and was not generally designed for wearing under clothes. Even so, the test instrument was sometimes used as a brace
15 for shorter periods.

- The present invention solves the above problems by providing an adjustable spinal brace which is easily and reproducibly positioned on the body of a patient thanks to a connection means having lateral iliac rolls which are fitted at the top of the pelvis bone. Also, it is easy to adjust the magnitude and position of the applied
20 pressure thanks to a lumbar pad provided with pressure setting means. Also, the lumbar pad may be positioned at different heights and the pressure point may be shifted in a lateral direction.

Summary of the invention

- 25 Thus, the present invention provides an adjustable spinal brace comprising an anterior abdominal pad and a posterior frame interconnected by a connection means.

- In accordance with the invention, the connection means comprises lateral iliac rolls to be positioned at the top of the pelvis bone (crista iliaca) and straps to be
30 connected to the anterior abdominal pad. The posterior frame has a lumbar pad provided with pressure setting means for adjusting the applied pressure.

The invention is defined in the accompanying claim 1 while preferred embodiments are set forth in the dependent claims.

35 Brief description of the drawings

The invention will be described in detail below with reference to the accompanying drawings, in which:

figure 1 is a dorsal perspective view of the spinal brace according to the invention,

figure 2 is a front view of the brace as worn on a patient with the skeleton bones visible,

figure 3 is a side view similar to figure 2,

5 figure 4 is a partially cut-away dorsal view of a screw jack design according to the invention,

figure 5A is a side cut-away view of the screw jack in a retracted position,

figure 5B is a side view of the screw jack in an extended position, and

10 figure 6 is a top detail view of the connection between the posterior and anterior parts.

10

Detailed description of preferred embodiments

The invention provides an adjustable spinal brace, especially a lumbar brace, which is multi-adjustable for conservative treatment of low back pain. The pain may have various causes, such as discogenic hernia, spinal stenose, spondylolisthesis etc.

15 The brace of the invention is a further development of the test instrument mentioned in the introduction, which is a tool to prove that conservative treatment could be effective. The present brace is designed for individual use during day and night. The design of the brace is virtually open at the lateral side, which allows for lateral bending. In general, the brace stabilises the spine in the sagittal plane.

20 One purpose of the brace is to stabilise the lumbar spine by the use of a "three point pressure" brace. Also, the brace restores lumbar lordosis to the individual needs by a multi-adjustable posterior lumbar pad.

A lightweight posterior frame bridges the lumbar spine from the distal end of the sacrum until the tenth thoracic vertebra T10, approximately two fingers below

25 the scapulae. Two iliac rolls, connected to the posterior frame, position this frame over the pelvis. In this situation the frame finds a reliable "grip" between the lower ribs and the pelvis, which can be maintained efficiently. The iliac rolls have virtually just "one" position where they can actually be. This is extremely important, since the adjustments of the posterior lumbar pad 2 and the accuracy of

30 this position after putting on the brace relies fully on the position of the iliac rolls, which at the same time will pull the abdominal pad into the soft tissue of the abdomen to create the third point in achieving the desired stabilisation of the lumbar spine. When properly applied to the body, the "three point pressure" will stabilise the lumbar spine into a more or less lordotic position with reduced lordosis. All

35 functional parts are integrated within the frame and do hardly interfere with activities like sitting, standing, walking or lying.

Figure 1 shows the brace according to the invention in a partially exploded view. The brace has a posterior frame 1 to be placed at the back of the patient. The frame 1 comprises two horizontal supports, a cranial support 5 and a caudal support

6. The horizontal supports 5, 6 are attached to two vertical H-shaped struts 12 by means of a respective set of screws.

The horizontal cranial support 5 can be adjusted vertically over a range of 50 mm. Also the caudal support 6 can be adjusted vertically over a range of 50 mm.

- 5 The total height of the frame 1 can be adjusted from 390 to 490 mm. This adjustment range is sufficient for 98 % of the population. The dimensions may of course be varied to provide other sizes.

In the centre of the posterior frame 1 two iliac rolls 3 are provided. The iliac rolls 3 are intended to be positioned at the crista iliaca, that is they will rest on top 10 of the pelvis bone. The iliac rolls are attached by means of elastic straps 4 and push buttons 19 to an anterior abdominal pad 7. Also the cranial and caudal supports 5, 6 may be connected with straps to the abdominal pad 7. Only one lower strap 4 is shown in figure 1. The posterior lumbar pad 2 is attached to the posterior frame 1 as is described more in detail with reference to figures 4, 5A and 5B.

15 Seen in a horizontal section, the vertical struts 12 consist of an "H" profile, with lateral openings. The shape of the struts 12 along the back of the patient is adapted to the anatomical shape of the human body. The openings and flanges of the "H" profile are useful for attachment of the horizontal supports 5, 6, the iliac rolls as well as a multi-adjustable posterior lumbar pad 2. For comfort the cranial 20 and caudal horizontal supports are padded with foam (not shown).

In figure 2, the brace is shown from the front as fastened on a patient. The skeleton bones on the patient are indicated for reference. As may be seen the iliac rolls and their straps 4 are located at the waist.

Figure 3 shows a similar view to figure 2 from the side. As is more clearly 25 seen in figure 3, the iliac rolls 3 are resting against crista iliaca (with some soft tissue in between).

Figure 4 is a dorsal view of the suspension mechanism for the posterior lumbar pad 2. See also figures 5A and 5B. The lumbar pad 2 is attached by means of a mounting plate 17. The mounting plate 17 has a shaft such that the pad 2 may 30 be rotated round a horizontal axis. The mounting plate 17 is connected by two pairs of legs 16 to the vertical struts 12. The legs 16 have pins 21 at the ends remote from the mounting plate 17. The pins are inserted in blocks 20 sliding in the H-shaped struts 12. Only the top blocks 20 are shown in figure 4. The blocks 20 may also carry set screws 9 for securing the lumbar pad 12 at a suitable height as is described 35 more in detail below.

The pins 21 are carried by or integral with a respective sleeve 22. The sleeve 22 also carries a bracket 13 with a row of holes 14. An adjustment screw 8 is fastened in one pair of the holes 14, normally the centre pair. As is shown, the screw 8 has a pair of oppositely directed threads, such that the distance between the

top and lower sleeve 22 may be adjusted accurately by screwing the screw 8. The screw 8 may be shifted to the left and right by using another pair of holes 14 for the reason described more in detail below.

- Figure 5A shows the lumbar pad 2 in its completely retracted position. In 5 this position the pad 2 is hardly touching the back of the patient but hidden in within the posterior frame 1. In figure 5B the pad is shown in an extended position. The maximum extension may be e.g. 50 mm.

- The iliac rolls 3 are connected via elastic straps 4 with push buttons 19, strings 10 and string locks 11 to the anterior abdominal pad 7 for applying the 10 abdominal pressure.

- In the embodiment shown in figure 6, the strings 10 may be guided around a respective pulley block 23. One end of the string is attached to the abdominal pad at the push button (via the strap 4) and the other end of the string is attached to the string lock 11 after tightening. The string lock 11 and pulley block 23 make it 15 possible to apply sufficient pressure in an efficient and easy way by tightening the strings 10 attached to the elastic straps 4 of the iliac rolls 3. This arrangement is easy to handle for the patient or doctor to achieve a sufficient tension and pressure.

- Figure 6 also shows how the iliac rolls are attached to the H-shaped struts with screws. As may be seen from figure 1, the iliac rolls carry a number of holes so 20 that the width of the brace is easily adjusted by using the set of holes providing the suitable width for the patient.

- The anterior abdominal pad 7 applies the abdominal lumbar pressure. It is a 25 lightweight concave pad, which should cover the abdomen from the symphysis up to the sternum point. From left lateral to right lateral the abdominal pad 7 should bridge the distance between the two iliac rolls 3. The cranial border of the pad is shaped after the lower ribs. The abdominal pad should be able to apply considerable pressure without changing shape and is therefore constructed out of a thermosetting composite. The pad may be tailored individually for the patient. The pad is furnished with (parts of) pushbuttons for attachment of the straps 4 and string locks 30 11 for the strings. For comfort the pad is lined with foam padding (not shown).

- Depending on the indication, the lordosis could be restored to the individual needs by means of the multi-adjustable posterior lumbar pad 2. In a non-functional position this lumbar pad will be hidden in the frame. Then, the three point pressure is applied by the horizontal support 5 and the horizontal caudal support 6 together 35 with the anterior abdominal pad 7.

The pad can be moved vertically by sliding in the H-shaped vertical struts 12. The pad itself is curved and somewhat flexible to follow the curvature of the lumbar portion of the back. For comfort the pad is lined with foam padding 18. It is suspended by means of a mounting plate 17 and a shaft such that it can turn around

- a horizontal axis. The centre can be positioned from vertebra L4 through T12; the most common area will be from L3 to L1. By means of the vertically placed adjusting screw 8, preferably a socket head cap screw, the posterior lumbar pad can be adjusted to apply pressure in the anterior direction. The lumbar pad 2 is
- 5 maintained at the suitable height by means of the pressure and friction against the back of the patient. As an alternative, set screws 9 can keep the lumbar pad in place.
- If the reaction force from the spine and soft tissue differs between left and right the mechanism will respond asymmetrically (like a trapezoid with two parallel vertical sides). If for instance the right vertical side is longer, the pressure at the
- 10 right side appears to be higher. By shifting the vertical adjusting screw to the right a compensation for this higher pressure can be accomplished. This way it becomes possible to balance the rotational forces of the spine.

A person with low back pain is in general fully capable in deciding in what level (height) and how strong (depth) the pad should be applied. Normally a good

15 starting position is to put the centre of the pad at the level of the L3 vertebra, which is at the 0-level (spine tangent to vertical) of the lordosis (without the compensation provided by the invention). The brace is put on by placing the iliac rolls at the crista iliaca and fastening the straps 4 by means of the push buttons. The straps are tightened by means of the strings 10 and the pulley blocks 23 and the string locks

20 11 such that a suitable pressure is obtained. If an enhanced stability against side bending is required, also the upper and lower straps 4 are attached to the cranial 5 and caudal supports, respectively. With the help of the screw-jack and a hexagon driver the doctor can apply pressure to the lumbar spine by means of the lumbar pad and restore lordosis against the pressure of the abdominal pad 7. Once the position

25 of the lumbar pad is set correctly, the patient may himself or herself doff and don the brace without requiring help.

The surface area of the anterior abdominal pad needs to be considerable bigger than the surface of the posterior lumbar pad. During forward bending the horizontal cranial 5 and caudal 6 support move away from the body and there is a

30 risk that the pressure of the dorsal pad becomes too high in relation to the pressure of the abdominal pad. The adjustments of the screw-jack can be used to compensate for the counter-pressure of the spine and the soft tissue. Asymmetrical pressure on the posterior lumbar pad will result in an asymmetrical position of the screw-jack. If a compensation of these forces is required the adjusting screw can be shifted to the

35 side where the pressure is highest, thus compensating and restoring the balance. Since the abdominal pressure acts as a counter pressure for all forces the user of the brace can feel these differences at his abdomen as a result of the higher pressure against the abdominal pad.

The following advantages of the invention may be mentioned:

- allowing an individual assessment of the shape of the lumbar lordosis giving a maximal pain relief;
 - 5 spine;
 - allowing a support in the optimal pain relieving level of the lumbar
 - 10 stabilising the device and preventing it from sliding up or down, which would move the dorsal plate up and down and thus loosing the level of optimal pain relief;
 - allowing a moderate side-bending of the trunk to improve the acceptance of the brace treatment;
 - allowing at least 90° bending of the hip joints i.e. when sitting in a car;
 - 15 - allowing an improved movement of the arms and the upper part of the trunk and avoiding unpleasant pressure of the upper edges of the device usually seen in conventional rigid braces.
- A preferred embodiment of the invention has been described in detail above. Many modifications as to the specific shape and materials used will be readily apparent to a person skilled in the art. The scope of the invention is only limited by the claims below.

13 -06- 2001

CLAIMS

1. An adjustable spinal brace comprising an anterior abdominal pad (7), a posterior frame (1) and lateral iliac rolls (3), said iliac rolls (3) to be positioned at the top of the pelvis bone (crista iliaca), and the abdominal pad (7) and the posterior frame (1) being interconnected by a connection means, **characterised** in that the connection means comprises said iliac rolls (3) and straps (4) to be connected to the anterior abdominal pad (7), and in that the posterior frame (1) has an adjustable lumbar pad (2) provided with pressure setting means (8) for setting the distance between the lumbar pad (2) and the posterior frame (1), thereby enabling an adjustment of the applied pressure.
2. A spinal brace according to claim 1, **characterised** in that the lumbar pad also (2) is adjustable in height.
3. A spinal brace according to claim 1 or 2, **characterised** in that the pressure setting means comprises a screw jack (8, 16).
4. A spinal brace according to claim 3, **characterised** in that the screw jack comprises a vertically placed adjusting screw (8).
5. A spinal brace according to claim 3 or 4, **characterised** in that the position of the screw (8) of the screw jack is adjustable in the lateral direction.
6. A spinal brace according to any of the previous claims, **characterised** in that the posterior frame (1) comprises two vertical struts (12), a cranial horizontal support (5) and a caudal horizontal support (6).
7. A spinal brace according to claim 6, **characterised** in that the cranial horizontal support (5) and the caudal horizontal supports (6) are adjustable in height.
8. A spinal brace according to any of the previous claims, **characterised** in that straps (4) are provided between the iliac rolls (3) and the abdominal pad (7).
9. A spinal brace according to claim 8 and 6 or 7, **characterised** in that straps (4) are provided between the horizontal supports (5, 6) and the abdominal pad (7).
10. A spinal brace according to any of the previous claims, **characterised** in that the anterior abdominal pad (7) is lightweight and concave and adapted to cover the abdomen substantially from the symphysis to the sternum point.
11. A spinal brace according to claim 10, **characterised** in that the cranial border of the anterior abdominal pad (7) is shaped after the lower ribs.



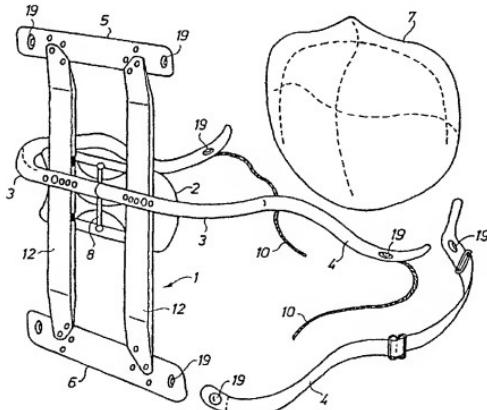
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(54) Title: ADJUSTABLE SPINAL BRACE

(57) Abstract

The invention relates to an adjustable spinal brace, which is multi-adjustable for conservative treatment of low back pain. The brace comprises an anterior abdominal pad (7) and a posterior frame (1) interconnected by a connection means. In accordance with the invention, the connection means comprises lateral iliac rolls (3) to be positioned at the top of the pelvis bone (crista iliaca) and straps (4) to be connected to the anterior abdominal pad (7). The posterior frame has a lumbar pad (2) provided with pressure setting means (8) for adjusting the applied pressure. The spinal brace is adjustable to enable an accurate magnitude and position of the pressure to correct the curvature of the spine, especially in the lumbar area. At the same time, the design of the brace is open at the lateral sides, which allows for lateral bending and normal movement of arms and legs.



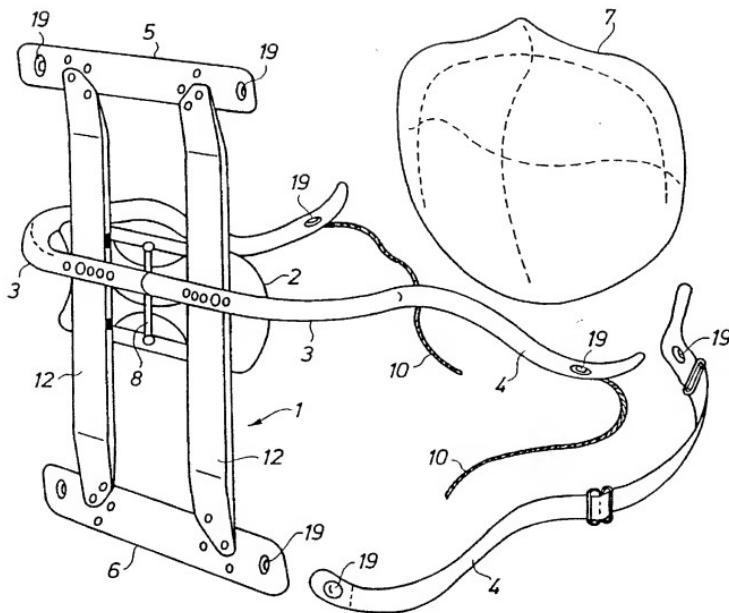


FIG. 1

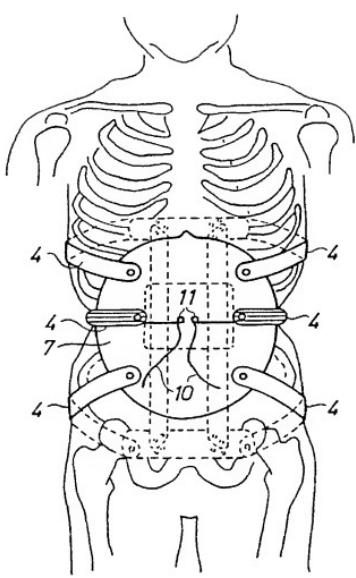


FIG. 2

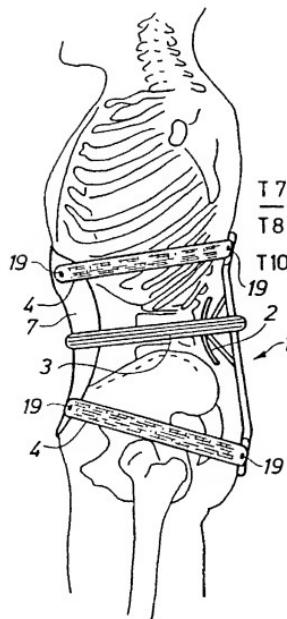


FIG. 3

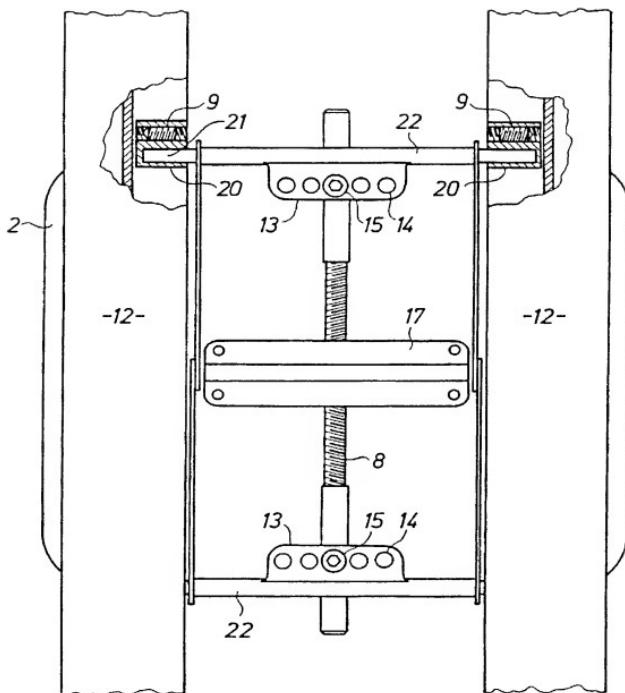


FIG. 4

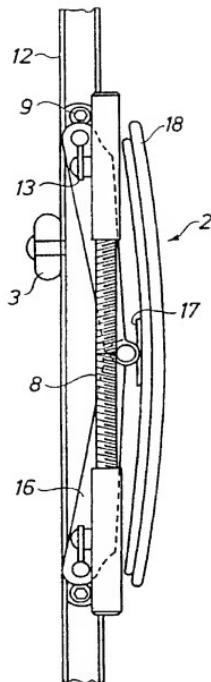


FIG. 5A

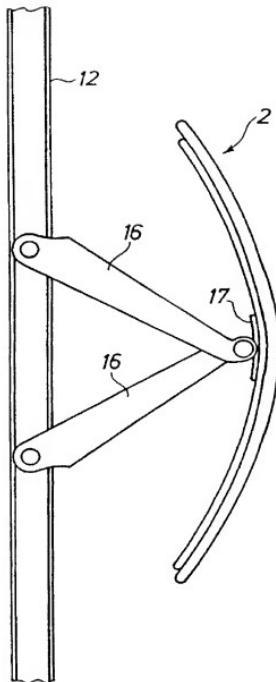


FIG. 5B

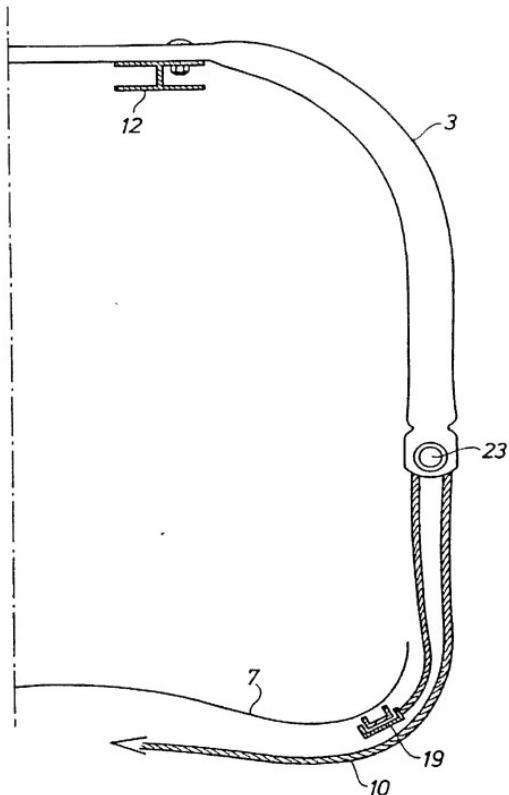


FIG. 6

SPECIFICATION IDENTIFICATION

the specification of which: (*complete (a), (b) or (c)*)

- (a) is attached hereto.
- (b) was filed on _____ as Serial No. _____ or
 Express Mail No. (*as Serial No. not yet known*) _____
and was amended on _____ (*if applicable*).

Note: Amendments filed after the original papers are deposited with the PTO that contain new matter are not accorded a filing date by being referred to in the Declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental Declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 CFR 1.67.

- (c) was described and claimed in PCT International Application No. PCT/SE00/00727 filed on 17 April 2000 and as amended on 13 August 2001.

ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in 37, Code of Federal Regulations, § 1.56,

(also check the following items, if desired)

- and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, and
- in compliance with this duty, there is attached an information disclosure statement, in accordance with 37 CFR 1.98.

PRIORITY CLAIM (35 U.S.C. § 119(a)-(d))

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

PATENT

Docket: CU-2691

COMBINED DECLARATION AND POWER OF ATTORNEY(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL,
CONTINUATION OR CIP)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATIONThis declaration is of the following type: (*check one applicable item below*)

- original
 design
 supplemental

Note: If the Declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application, do *not* check next item; check appropriate one of last three items.

- national stage of PCT

Note: If one of the following 3 items apply, then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR CIP.

- divisional
 continuation
 continuation-in-part (CIP)

INVENTORSHIP IDENTIFICATION

WARNING: If the inventors are each not the inventors of all the claims, an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

TITLE OF INVENTIONADJUSTABLE SPINAL BRACE

(complete (d) or (e))

- (d) no such applications have been filed.
 (e) such applications have been filed as follows.

Note: Where item (c) is entered above and the international application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.

**PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION
AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119(a)-(d)**

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING (day/month/year)	PRIORITY CLAIMED UNDER 35 USC 119
Sweden	9901556.2	30 April 1999	<input checked="" type="checkbox"/> YES NO <input type="checkbox"/>
			<input type="checkbox"/> YES NO <input type="checkbox"/>

**CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)
(35 U.S.C. § 119(e))**

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

PROVISIONAL APPLICATION NUMBER	FILING DATE

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(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION**

Note: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CIP APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. § 120.

Full name of second joint inventor

Jan
(Given Name) F.A.
(Middle Initial or Name) SMITS
(Family (or Last) Name)

Inventor's signature _____

Date 12-11-01 Country of Citizenship Netherlands

Residence Helmond, The Netherlands NL

Post Office Address Holterbergweide 26, NL-5709 MP Helmond, The Netherlands

100009860 - 052002

ADDED PAGE TO COMBINED DECLARATION & POWER OF ATTORNEY FOR SIGNING
BY ADMINISTRATOR(TRIX), EXECUTOR(TRIX) OR LEGAL REPRESENTATIVE ON
BEHALF OF DECEASED OR INCAPACITATED INVENTOR (37-CFR 1.42 & 1.43)

301 I Eva WILLNER, hereby declare I am a citizen of Sweden residing at Remontgatan 50, SE-212 35 Malmo, Sweden and that I am executing and signing the declaration to which this is attached as heiress of the deceased inventor, Stig WILLNER.

SE That, upon information and belief, I aver those facts that the inventor is required to state.

17. 11. 01

Date

Eva Willner
Eva WILLNER

POWER OF ATTORNEY

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith (*list name and registration number*).

Thomas F. Peterson, 24790; Richard J. Streit, 25765; Donald P. Reynolds, 26220; W. Dennis Drehkoff, 27193; Vangelis Economou, 32341; Brian W. Hameder, 45613; Valerie Neymeyer-Tynkov, 46956; Paul B. West, 18947; Joseph H. Handelman, 26179; Peter D. Galloway 27885; John Richards, 31503; Iain C. Baillie, 24090; Richard P. Berg, 28145

Attached, as part of this declaration and power of attorney, is the authorization of the above-named practitioner(s) to accept and follow instructions from my representative(s).

SEND CORRESPONDENCE TO:

Richard J. Streit
c/o Ladas & Parry
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DIRECT TELEPHONE CALLS TO:

(*Name and telephone number*)

(312) 427-1300

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

Note: Carefully indicate the family (or last) name, as it should appear on the filing receipt and all other documents.

Full name of first joint inventor

Stig _____ (Given Name) _____ (Middle Initial or Name) _____ WILLNER
 (Family (or Last) Name)

Inventor's signature _____ (deceased - see added page)

Date _____ Country of Citizenship _____

Residence _____

Post Office Address _____